

all  
mixture components in accordance with a flow-rate ratio of reagent-mixture components corresponding to each respective selected reagent mixture.

### Remarks

Claims 2 and 32 have been canceled, claims 1, 3, 31-39, and 42 have been amended, new claim 43 has been added, and therefore claims 1, 2-6, 31 and 33-44 are pending in this application. In view of the above amendments and the following remarks, it is respectfully submitted that these claims are allowable.

Claims 1-6, 40 and 42-43 stand rejected under the judicially-created doctrine of obviousness-type double patenting in view of Applicant's prior U.S. Patent No. 5,840,254. Accordingly, Applicant will submit an appropriate terminal disclaimer upon receiving an indication of allowable subject matter.

Claims 1-6 and 31-43 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hansen et al. (U.S. No. 4,022,575), Cruzan (U.S. No. 4,036,062), and Parrent et al. (U.S. No. 4,920,060). The Examiner's grounds for rejection are hereinafter traversed, and reconsideration is respectfully requested, particularly in view of the clarifying amendments to the claims.

None of the cited references teach or suggest an apparatus or method which forms a plurality of different selected reagent mixtures by adjusting the flow rate of at least one of the reagent-mixture components in accordance with a respective flow-rate ratio forming each selected reagent mixture, as recited in amended independent claims 1 and 31. To the contrary, the cited references show no recognition of creating different selected reagent mixtures, much less creating such mixtures by adjusting the flow-rate ratio to form each mixture.

In Cruzan, a first conduit having a first volume is filled with diluent, and a second conduit having a volume bearing a predetermined size relationship to the first volume is filled with a sample. (See, e.g., column 1, lines 57-62 of Cruzan.)

Accordingly, the flow-rate ratio is fixed by the relative volumes of the two conduits, and there is no teaching or suggestion of adjusting the flow-rate ratio as recited in amended independent claims 1 and 31.

In Parrent, Jr. et al., the sample is introduced through a membrane 23 into the diluent stream, and the concentration of the resulting mixture is controlled by the pressure applied to the sample to force it through the membrane. In Hansen et al., on the other hand, the injector 24 defines a series of bores 32 for receiving hypodermic needles for injecting the samples into the carrier stream traveling through the line 25. Thus, neither of these references teaches or suggests adjusting the flow-rate ratio to form a plurality of different selected reagent mixtures, as recited in amended independent claims 1 and 31.

This claimed feature provides significant advantages over the prior art. One advantage is that the mixture ratio of the reagent mixture may be adjusted at any time, either before or during analysis, by adjusting the flow-rate ratio of the reagent-mixture components. (See page 18, lines 14 through 27 of the present specification.) As also described in the present specification, if, for example, a blood-cell abnormality is detected during hematologic analysis, the blood-dilution ratio (which defines the reagent mixture) may be adjusted to further assess the abnormality. With the prior art apparatus, on the other hand, in which the sample batches are prepared in mixing cuvettes, this would require additional samples to be taken or used to further assess the abnormalities. Id. Another advantage of creating the reagent mixtures in this manner (as opposed, for example, to using a mixing cuvette), is that a lesser volume of the reagent-mixture components (e.g., blood samples) may be employed. (See page 18, lines 1 through 13 of the present specification.) Yet another advantage of this claimed feature is that in the veterinary market, for example, the system may automatically make the different reagent mixtures for a variety of different animal species by adjusting the flow-rate ratios in accordance with, for example, a database of information pertaining to the reagent-mixture

ratios for the different species. (See page 14, lines 16 through 24, and claim 5 of the present specification.)

Neither these advantages, nor the solution of the present invention for achieving these advantages, as specifically defined in amended independent claims 1 and 31, are taught or suggested by the cited prior art.

Independent claim 42 is directed more specifically to the mixing chamber and the structure for creating turbulence and mixing the reagent components in the chamber. Independent claim 42 recites an elongated mixing chamber having a first inlet port for introducing a first reagent-mixture component at an upstream end of the mixing chamber, and a second inlet port located downstream of the first inlet port for introducing a second reagent-mixture component, wherein at least one of the first and second inlet axes is inclined at an acute angle relative to the other and the elongated axis of the mixing chamber for introducing the respective reagent-mixture component stream into the mixing chamber in a different flow direction than the other reagent-mixture components to thereby create turbulence in the combined reagent-mixture stream. One advantage of this feature is that it creates a more even gradient of lytic shock, particularly when there are several inlet ports for simultaneously introducing several reagent-mixture components into the mixing chamber.

With prior art mixing cuvettes or chambers, in which a blood/diluent sample and various lytic reagents are combined in a mixing cuvette, there is typically a higher concentration of lytic reagents in the portion of the cuvette where the reagents are introduced, thus causing the lytic reagents to have a varying effect on the blood sample throughout the sample batch. (See page 3, lines 5 through 17 of the present specification.) In the system of the invention as recited in claim 42, on the other hand, because the reagent-mixture components are introduced in a staggered relationship (the second inlet port is located downstream of the first in the manner claimed), and the second inlet port is oriented transverse to the elongated direction of the chamber, the reagents are more

thoroughly and uniformly mixed in the combined reagent-mixture stream, thus creating a more homogenous reagent mixture and avoiding an uneven gradient of lytic shock.

Neither these advantages, nor the specific structural features recited in amended independent claim 42 giving rise to these advantages, are taught or suggested by Cruzan, Hansen et al. or Parrent et al.

It is therefore respectfully submitted that amended independent claims 1, 31 and 42 are not anticipated by Cruzan, Hansen et al. or Parrent, Jr. et al., for at least these reasons. Because claims 2-6, 32-41 and 43 each depend from either independent claim 1, 31 or 42, it is respectfully submitted that these dependent claims likewise are not anticipated by the references of record for at least the same reasons as the independent claims, and for reciting additional patentable subject matter.

Accordingly, it is respectfully submitted that claims 1-6 and 31-44 are allowable. All issues raised by the Examiner having been addressed, an early action to that effect is earnestly solicited.

An Information Disclosure Statement citing additional prior art references of record in the parent application (serial no. 458,701, now U.S. Patent No. 5,840,254) is submitted herewith. These references are cited at this time because they are now believed to be relevant to the claims as presently amended. Accordingly, it is respectfully submitted that the Examiner indicate consideration of the cited references by returning a copy of the enclosed form PTO-1449 with initials or other appropriate marks.

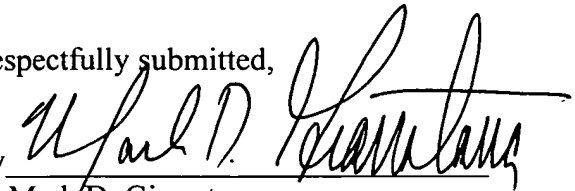
No fee in addition to that submitted herewith is believed to be required. However, if any additional fees are required, or otherwise if necessary to cover any

deficiency in fees already paid, authorization is hereby given to charge our Deposit

Account No. 11-0231.

Respectfully submitted,

By



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